



UNITED STATES PATENT AND TRADEMARK OFFICE

CK

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------|-------------|----------------------|----------------------|------------------|
| 10/595,890 | 07/24/2006 | Didier Courtois | 112701-727 | 8593 |
| 29157 | 7590 | 12/13/2007 | EXAMINER | |
| BELL, BOYD & LLOYD LLP | | | MACAULEY, SHERIDAN R | |
| P.O. Box 1135 | | | ART UNIT | PAPER NUMBER |
| CHICAGO, IL 60690 | | | 1651 | |
| NOTIFICATION DATE | | DELIVERY MODE | | |
| 12/13/2007 | | ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

| | | | |
|------------------------------|----------------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/595,890 | COURTOIS ET AL. | |
| | Examiner Sheridan R. MacAuley | Art Unit 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 November 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-11 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-11 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 18 May 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>11/20/2006</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-11 are pending and examined on the merits in this office action.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. In claim 1, it is unclear whether applicant intends for the cell culture apparatus or the wave induction mechanism to "lift between 5 and 50% of the length of the cell culture chamber". Because the term is on a separate line, it is unclear if this term is meant to modify the apparatus or the wave induction mechanism.
4. Claims 2-7, 10 and 11 are indefinite insofar as they depend from claim 1.
5. In claim 2, it is also unclear how applicant intends for the wave induction mechanism to "move from 8 to 20% of the surface area of the lower part of the culture chamber". For example, the mechanism could move from supporting 8% of the surface area to supporting 20% of the surface area, it could be actively involved in moving only 8-20% of the surface area, or only 8-20% of the surface area could be moved by the mechanism.
6. In claim 5, it is also unclear how applicant intends for the apparatus to lift "alternately between 5 and 50% of the length of the culture chamber". For instance, the

apparatus might alternate between lifting 5% of length of the chamber and lifting 50% of the length of the chamber, or it may lift the same amount each time alternately (i.e. alternate between lifting and not lifting).

7. In claims 7 and 11, the term "filling rate" also renders the claims indefinite. It is unclear how applicant intends to achieve the desired filling rate of between 10-80%, or 20-40%. The term "filling rate" is also a relative term which renders the claims indefinite because the term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For example, a filling rate of 10-80% could mean that the chamber may be full to 10-80% of its total volume, that the flux of the solution through the chamber is between 10% and 80% of a maximum amount that is not defined in the specification, or that the rate of filling increases from 10% of the maximum to 80% of the maximum.

8. Claims 8 and 9 provides for the use of a cell culture apparatus but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Although each claim recites that the method "comprises the steps of", the only "step" that is recited is the use of the cell culture apparatus.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 8 and 9 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). Although each claim recites that the method "comprises the steps of", the only "step" that is recited is the use of the cell culture apparatus.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Singh (US 6,190,913). Claim 1 recites a cell culture apparatus comprising a flexible culture chamber, and a wave induction mechanism, that lifts up between 5 and 50% of the length of the culture chamber. Claim 2 recites the cell culture apparatus according to

claim 1, wherein the wave induction system moves from 8 to 20% of the surface area of the lower part of the culture chamber. Claim 3 recites the cell culture apparatus according to claim 1, wherein the wave induction mechanism moves part of the lower part of the culture chamber to an angle of 1 to 90 degrees. Claim 4 recites the cell culture apparatus according to claim 1, wherein the culture chamber comprises means to circulate air. Claim 5 recites the cell culture apparatus according to claim 1, wherein the wave induction mechanism lifts up alternatively between 5 and 50% of the length of the culture chamber. Claim 6 recites the cell culture apparatus according to claim 1, wherein the culture chamber is a flexible plastic bag. Claim 7 recites the cell culture apparatus according to claim 1, wherein the culture chamber filling rate is from 10 to 80%. Claim 8 recites a method for cultivating plant cells, animal cells, or microorganisms comprising the steps of using a cell culture apparatus that comprises a flexible culture chamber, and a wave induction mechanism that lifts up between 5 and 50% of the length of the culture chamber. Claim 9 recites a method for producing biomass cells, embryogenic plant cells, metabolites, secondary plant metabolites and/or recombinant molecules comprising the steps of using a cell culture apparatus that comprises a flexible culture chamber, and a wave induction mechanism that lifts up between 5 and 50% of the length of the culture chamber to produce biomass cells, embryogenic plant cells, metabolites, secondary plant metabolites and/or recombinant molecules. Claim 10 recites the cell culture apparatus according to claim 1 wherein the wave induction mechanism moves part of the lower part of the culture chamber to an

angle of 1 to 25 degrees. Claim 11 recites the cell culture apparatus according to claim 1 wherein the culture chamber filling rate is from 20 to 40%.

13. Singh teaches a cell culture apparatus comprising a flexible cell culture chamber (such as a plastic bag) and a wave induction mechanism (abstract, fig. 1). Singh teaches that the wave induction mechanism is a pivot point which alternately rocks each side of the cell culture chamber, i.e. 50% of the cell culture chamber is lifted alternately (col. 4, lines 7-17, fig. 1). The pivot point (i.e. wave induction mechanism) in the method of Singh does not occupy more than 20% of the surface area of the cell culture chamber in the embodiment shown in fig. 1. Singh teaches that the wave induction mechanism moves the cell culture chamber between one and fifteen degrees (col. 4, lines 18-21). Singh teaches that the liquid phase may comprise 10 to 80% of total bag volume; as is clear from the figures, Singh anticipates the bag volume to be approximately 20 to 40% (col. 4, lines 30-34, figs. 1-3). Singh teaches that the cell culture chamber comprises a means to circulate air (col. 4, lines 34-49). Singh teaches a method of cultivating plant, animal, insect or microbial cells (i.e. biomass cells) using the apparatus (abstract).

14. Therefore, Singh anticipates all of the limitations of the cited claims.

15. Claims 1-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Hubbard (US 2005/0063250 A1). Claim 1 recites a cell culture apparatus comprising a flexible culture chamber, and a wave induction mechanism, that lifts up between 5 and 50% of the length of the culture chamber. Claim 2 recites the cell culture apparatus according to claim 1, wherein the wave induction system moves from 8 to 20% of the

surface area of the lower part of the culture chamber. Claim 3 recites the cell culture apparatus according to claim 1, wherein the wave induction mechanism moves part of the lower part of the culture chamber to an angle of 1 to 90 degrees. Claim 4 recites the cell culture apparatus according to claim 1, wherein the culture chamber comprises means to circulate air. Claim 5 recites the cell culture apparatus according to claim 1, wherein the wave induction mechanism lifts up alternatively between 5 and 50% of the length of the culture chamber. Claim 6 recites the cell culture apparatus according to claim 1, wherein the culture chamber is a flexible plastic bag. Claim 7 recites the cell culture apparatus according to claim 1, wherein the culture chamber filling rate is from 10 to 80%. Claim 8 recites a method for cultivating plant cells, animal cells, or microorganisms comprising the steps of using a cell culture apparatus that comprises a flexible culture chamber, and a wave induction mechanism that lifts up between 5 and 50% of the length of the culture chamber. Claim 9 recites a method for producing biomass cells, embryogenic plant cells, metabolites, secondary plant metabolites and/or recombinant molecules comprising the steps of using a cell culture apparatus that comprises a flexible culture chamber, and a wave induction mechanism that lifts up between 5 and 50% of the length of the culture chamber to produce biomass cells, embryogenic plant cells, metabolites, secondary plant metabolites and/or recombinant molecules. Claim 10 recites the cell culture apparatus according to claim 1 wherein the wave induction mechanism moves part of the lower part of the culture chamber to an angle of 1 to 25 degrees. Claim 11 recites the cell culture apparatus according to claim 1 wherein the culture chamber filling rate is from 20 to 40%.

16. Hubbard teaches a cell culture apparatus comprising a flexible culture chamber (i.e. a fermentor) and a wave induction mechanism (a bag that is capable of being selectively pressurized and deflated; abstract). Hubbard teaches that the wave induction mechanism may be located under a portion of the bag, and alternately lifts between 5 and 50% of the bag shown in fig. 4 (p. 2, par. 34, fig. 4, p. 3, par. 51). The bag shown in fig. 4 is lifted at an angle of between 1 and 90 degrees. Hubbard teaches that the culture chamber may be a flexible plastic bag and that the culture chamber comprises a means to circulate air (p. 2, par. 30, p. 3, par. 45). Hubbard teaches that the bags may be filled from 20 to 80% of the bag volume (p. 2, par. 29). Hubbard teaches that the apparatus may be used in a method for producing biomass cells, such as microorganisms (p. 2, par. 29).

17. Therefore, Hubbard anticipates all of the limitations of the cited claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan R. MacAuley whose telephone number is (571) 270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM



RUTH DAVIS
PRIMARY EXAMINER